Subsec. (j). Pub. L. 108–214, § 2(d)(2)(B)(iv), substituted ''subsection (a)(2)(D)'' for ''subsection (a)(1)(D)''.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–144 effective Oct. 1, 2012, with fees under this subpart to be assessed for all submissions listed in subsection (a)(2)(A) of this section received on or after Oct. 1, 2012, see section 206 of Pub. L. 112–144, set out as a note under section 379i of this title.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective Oct. 1, 2007, except for certain premarket fees under this subpart, see section 216 of Pub. L. 110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2017, see section 207(a) of Pub. L. 112–144, set out as a note under section 379i of this title.

Section effective Oct. 26, 2002, except for certain premarket fees, see section 106 of Pub. L. 107–250, set out as a note under section 379i of this title.

FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS

Pub. L. 107–250, title I, § 102(b), Oct. 26, 2002, 116 Stat. 1600, as amended by Pub. L. 108–214, § 2(d)(2)(C), (3)(B), Apr. 1, 2004, 118 Stat. 577, provided that: ''A person submitting a premarket report to the Secretary of Health and Human Services is exempt from the fee under section 738(a)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j(a)(2)(A)(ii)] (as added by subsection (a) of this section) if—

''(1) the premarket report is the first such report submitted to the Secretary by the person; and

''(2) before October 1, 2002, the person submitted a premarket application to the Secretary for the same device as the device for which the person is submitting the premarket report.''

§ 379j–1. Reauthorization; reporting requirements

(a) Reports

(1) Performance report

(A) In general

Beginning with fiscal year 2013, for each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(B) Publication

With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments Act of 2012, the Secretary shall make such information publicly available on the Internet Web site of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

(C) Updates

The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) Fiscal report

For fiscal years 2013 through 2017, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(3) Public availability

The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

(b) Reauthorization

(1) Consultation

In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) Prior public input

Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) Periodic consultation

Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

(4) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) Transmittal of recommendations

Not later than January 15, 2017, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) Minutes of negotiation meetings

(A) Public availability

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) Content

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, § 738A, as added Pub. L. 110–85, title II, § 213, Sept. 27, 2007, 121 Stat. 850; amended Pub. L. 112–144, title II, § 204, July 9, 2012, 126 Stat. 1006.)

TERMINATION OF SECTION

For termination of section by section 207(a) of Pub. L. 112–144, see Effective and Termination Dates note below.

REFERENCES IN TEXT

Section 201(b) of the Medical Device User Fee Amendments of 2012, referred to in subsec. (a)(1)(A), (B), is section 201(b) of Pub. L. 112–144, which is set out as a note under section 379i of this title.

AMENDMENTS

2012—Subsec. (a)(1). Pub. L. 112–144, § 204(b)(1), added par. (1) and struck out former par. (1). Prior to amendment, text read as follows: ''For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.''

Subsec. (a)(2). Pub. L. 112–144, § 204(b)(2), substituted ''2013 through 2017'' for ''2008 through 2012''.

Subsec. (b)(1). Pub. L. 112–144, § 204(a)(1), substituted ''2017'' for ''2012''.

Subsec. (b)(5). Pub. L. 112–144, § 204(a)(2), substituted ''2017'' for ''2012''.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–144 effective Oct. 1, 2012, with fees under this subpart to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2012, see section 206 of Pub. L. 112–144, set out as a note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Jan. 31, 2018, see section 207(a) of Pub. L. 112–144, set out as a note under section 379i of this title.

Section effective Oct. 1, 2007, except for certain premarket fees under this subpart, see section 216 of Pub. L. 110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379i of this title.

SUBPART 4—FEES RELATING TO ANIMAL DRUGS

§ 379j–11. Definitions

For purposes of this subpart:

(1) The term ''animal drug application'' means an application for approval of any new animal drug submitted under section 360b(b)(1) of this title. Such term does not include either a new animal drug application submitted under section 360b(b)(2) of this title or a supplemental animal drug application.

(2) The term ''supplemental animal drug application'' means—

(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 360b(c)(2) of this title for which data with respect to safety or effectiveness are required.

(3) The term ''animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

(4) The term ''animal drug establishment'' means a foreign or domestic place of business